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10/566,305	02/23/2006	James M. Davenport	SALTER P47AUSP1	1903
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EXAMINER				
OSTRUP, CLINTON T				
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3771				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/566,305

**Applicant(s)**

DAVENPORT ET AL.

**Examiner**

CLINTON OSTRUP

**Art Unit**

3771

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-11 and 13-44 is/are pending in the application.
- 4a) Of the above claim(s) 20-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13-19 and 44 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☒ Claim(s) 1,3-11 and 13-44 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 11/3/2010
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to the Amendment filed October 26, 2010. As directed by the amendment, claims 1, 3-9, 11, 13-28, and 36-42 have been amended; claim 44 has been added; and claims 2, 12, and 43 are cancelled. Thus, claims 1, 3-11, 13-42, and 44 are pending in this application with claims 20-42 being withdrawn from consideration. Therefore, claims 1 and 3-11, 13-19 and 44 are presented for examination on the merits.

### ***Election/Restrictions***

2. This application contains claims 20-42 drawn to an invention nonelected without traverse in the reply filed on October 23, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

4. Claim 44 is objected to because of the following informalities: claim 44 is objected to because it is unclear what is meant by "each head being large in size than the supply line". For examination purposes, the word "large" was read as "larger" however, appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 7-11, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payton (4,660,555) in view of Simmons et al. (5,752,511).

Regarding claims 1 and 11, Payton discloses a nasal cannula (figures 1 and 10-12) for supplying a respiratory gas (oxygen) to a patient, the nasal cannula comprising a supply line (41) which has a head (conical end 42) adjacent a leading end (distal end) thereof with a discharge opening (24a) therein for discharging a respiratory gas (oxygen), and an opposite end (distal end) of the supply line (41) being connectable (capable of being connected) to a respiratory gas source (via 36); wherein the head (42) is formed integrally with and from the same material as the pair of supply line (col. 5, lines 36-40) and each head is sized to be snugly received and retained within one of the nasal cavities of the patient (figure 1), an exterior surface of the head (42) has a plurality elongate troughs (45) formed therein, and the plurality elongate troughs (45) form, once insert into the respective nasal cavity, a plurality of leakage passages (passages allow for gas in or out), between a portion of inwardly facing nasal cavity skin of the patient (figure 1) and the plurality elongate troughs (45) of the head (42), to facilitate exhausting of excess respiratory gas supplied to the patient through the leakage passage (45) while maintaining a positive pressure (via air supplied to the nasal passages via 36 to the

cone shape (42) of the device shown in figures 10-12 and the interaction with the interior of the patients nasal cavities as shown in figure 1) within a respiratory passage of the patient at least during exhalation by the patient (gas is allowed to enter the nasal passages via 45 and 20a but would be exhaled through the passages 45 in the device shown in figures 10-12; thus, a positive pressure would inherently be created as the patient exhales from the nasal passages). See: figures 1 and 10-12 and col. 5, lines 9-40.

However, Payton lacks a device with a pair of supply lines with each supply line having a head, as claimed.

Simmons teaches a retainer clip assembly that can be used for delivering supplemental oxygen using standard oxygen tubing and a common oxygen supply tube that delivers oxygen to both nasal passages which is commonly referred to as an oxygen cannula. See: col. 4, lines 33-40; col. 5, lines 53-64 and figures 2-4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used two supplemental oxygen delivery devices disclosed by Payton, connected to a retainer clip, as taught by Simmons, in order to provide an oxygen delivery device that deliver supplemental oxygen to a both nasal airways of a patient, thereby enhancing the delivery of supplemental oxygen while the air passages simultaneously allow for passage of air so that respiratory gas can be respired in case of mechanical failure of the supplemental oxygen delivery system.

Regarding claim 7, the nasal cannula of the combined references has the pair of supply lines (two 41s of Paton) are connected with one another by a central bridge

member (middle portion of retainer clip 14 taught by Simmons) having an axial length that spans no more than a width of a philtrum of the patient (see figures 3 and 4, but it should also be recognized that the width of the claims device would vary depending on the patient being treated for example an infant would have a significantly different size philtrum than an adult, however a skilled artisan would choose a device to fit the patient being treated).

Regarding claims 8 and 18, the device of the combined references discloses a nasal cannula with supply lines (41 of Payton) and the heads (42 of Payton) that are manufactured from a flexible material (col. 5, lines 36-40 of Payton) and the second end of each of the supply lines bends (41 is an elbow and by placing the device in the clip of Simmons, they would bend away from each other analogous to the device shown in figure 4 of Simmons) away from one another.

Regarding claims 9 and 19, the nasal cannula of the combined references has a second end (distal end of 41) of each of the supply lines (41) is coupled to an auxiliary respiratory gas supply line (36 of Payton which corresponds to 38 of Simmons) and at least the second end of each of the supply lines is curved to pass beneath a patient's cheekbone area when the nasal cannula is donned by a patient. See: figure 1 of Payton and figure 4 of Simmons.

Regarding claim 10, the nasal cannula of the combined references discloses a central bridge member (middle portion of the clip 14 taught by Simmons) aligns the pair of supply lines (14 of Simmons) parallel to one another (when nasal cannulas of Payton are placed into clip of Simmons) to facilitate insertion of the heads (42 of Payton),

carried by the ridge (40 of Payton) of the pair of supply lines (41 of Payton), within the nostrils of the patient. See: figure 1 of Payton and figures 2-4 of Simmons).

7. Claims 3-6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payton (4,660,555) and Simmons et al. (5,752,511), as applied to claim 1 above, and further in view of Kahn et al. (5,105,807).

The combined references disclose all the limitations of claims 3 and 13, except exterior surface of the head has between six and eight elongate troughs formed therein which are equally spaced about a circumference of the head, and each of the elongate troughs partially defines one of the leakage passages in the head to facilitate exhausting of the excess respiratory gas and inhalation of any room air required by the patient.

Kahn teaches a disposable nasal anchoring system with various shapes that can be used as a compressible sleeve and that modifications of the sleeve can be adapted according to need or desirability. See: col. 3, lines 38-46 and figures 4a-4g. Kahn specifically teaches a compressible sleeve (figure 4g) that has an exterior surface (outer surface) of the head (compressible sleeve) has a plurality elongate troughs (formed between ridges) formed therein for partially defining a plurality of leakage passages ("channels can additionally be formed between the outside of the sleeve 8 and the inside of the nostril by irregularly shaped sleeves") therein to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g. Kahn teaches that the exterior surface of the head taught in figure 4g of Kahn has between six and eight elongate troughs (formed between

ridges) formed therein which are equally spaced about a circumference of the head, and each of the elongate troughs partially defines one of the leakage passages in the head to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of the combined references by using star shapes nasal inserts with additional channels surrounding the nasal inserts, as taught by Kahn, because of the reasonable expectation that a conical star shaped nasal insert with exterior channels would perform equally as well as a conical shape with semi-cylindrical cut-out exterior channels in providing channels to allow gas to pass between the nasal cannula and the skin of the inner nose of a user.

Regarding claims 4 and 14, each of the plurality elongate troughs of Kahn is formed by a pair of adjacent planar side surfaces (sides of exterior walls) which diverge away from a common elongate valley (lowest most point of troughs) toward a pair of spaced apart but adjacent elongate ridges (upper most point of exterior surfaces) to partially define one of the plurality of leakage passages. See: col. 5, lines 29-43 and figure 4g.

Regarding claims 5-6 & 15-16, the combined references lack the specific teaching that each one of the leakage passages has a cross sectional open area of between about 0.002 square inches (0.013 cm<sup>2</sup>) and 0.0055 square inches (0.035 cm<sup>2</sup>), as claimed in claim 5; or, wherein each head has a maximum width dimension of between about 0.345 of an inch (0.88 cm) about 0.70 of an inch (1.8 cm) and a length of



between about 0.30 of an inch (0.76 cm) and about 0.60 of an inch (1.5 cm); however, Kahn specifically describes how modifications of the sleeve can be adapted according to need or desirability and it a change in the size or shape of a prior art device is a design consideration well within the skill of the art.

8. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payton (4,660,555) and Simmons et al. (5,752,511) and further in view of Zimmerman (4,273,124).

The combined references disclose all the limitations of claims 17 and 44, except the central bridge member being formed integral with and from the same material as the supply lines and the heads.

Zimmerman teaches nasal inserts may be formed integrally with gas supply lines (figure 2) or they can be joined together as separate components (figure 4) and specifically teaches a dual nasal insert with a connecting bridge member (figure 7). See: col. 3, lines 45-53 and col. 5, lines 15-24. Thus, forming of a one piece construction instead of separate components would be merely a matter of an obvious engineering choice to one having ordinary skill in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nasal cannula of the combined references, by forming the device into integrally, as taught by Zimmerman, because of the reasonable expectation that a skilled artisan would readily recognize that the device could be formed as a one piece construction instead of separate components as this would be merely a matter of an obvious engineering choice to one having ordinary skill

in the art. Moreover, a device formed integrally from a single material would be reasonably expected to perform equally as well as a device formed of separate components connected together.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1, 3-11, 13-19 and 44 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771